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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,976	12/06/2000	Avi Kulkarni	P1482USA	7355

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EXAMINER

PORTER, RACHEL L

ART UNIT PAPER NUMBER

3626

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,976

Applicant(s)

KULKARNI, AVI

Examiner

Rachel L. Porter

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MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 12/6/00. Claims 1-17 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-17 recite first and second modules. It is unclear to the Examiner whether the claimed modules are software components or medical hardware components. Moreover, the specification does not use or refer to the term "module" to describe any aspect of the claimed device or system. For the purposes of applying art, the Examiner will interpret the term to mean any component of a medical system.

Claim 7 recites the limitation "the first module" in line. There is insufficient antecedent basis for this limitation in the claim. Claim 7 recites only a module, but not multiple modules or a first module. It is unclear with the recitation of "the first module" if the applicant intended to claim multiple modules in the present claim.

Claims 8-13 inherit the deficiencies of claim 7 through dependency, and are also rejected.

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Furthermore, claim 12 recites "a second module adapted to receive the first module" and "a device for accessing the first module." It is unclear to the Examiner 1) how these components are distinct from one another and 2) what the first module is receiving from the second module. For the purposes of applying art, the Examiner will interpret this claim to mean the various system components can exchange data.

Claim 13 recites the limitation "the device of the claim 7 wherein the device for accessing the second module is ...". There is insufficient antecedent basis for this limitation in the claim. Claim 7 does not recite a device a second module or a device for accessing the second module.

Claim 14 recites, "a first module adapted to receive a second module" and "a second module adapted to receive the first module". Again, it is unclear to the Examiner how the modules "receive" one another, and whether the applicant intends to claim a physical connection between components or whether the modules are receiving data from another. Claims 15-17 inherit the deficiencies of claim 14 through dependency and are also rejected.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-7, 9-12, 14, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Ridgeway (USPN 5,967,975).

[claim 1] Ridgeway teaches a method for acquiring data related to a person's healthcare habits comprising the steps of:

- (a) setting data trigger types and values; (Figure 2, col. 10, lines 2-19; lines 65-67)
- (b) collecting data from a device; (col. 9, lines 19-33)
- (c) monitoring data trigger values; (col. 10, lines 20-23)
- (d) setting data owner identifiers; (col. 10, lines 4-19)
- (e) transmitting the data and data owner identifiers electronically to a remote central location for processing; and (col. 10, lines 33-45; lines 51-67)
- (f) providing access to the data from various other remote locations over a network. (col. 9, lines 19-33)

[claim 2] Ridgeway teaches a method wherein collecting data includes collecting data from dumb devices without computing power. (col. 10, lines 63-65—collected data sent to central processor for limit checking)

[claim 3] Ridgeway teaches a method wherein collecting data includes collecting data automatically from devices that have computing power and associated electronics. (col. 10, lines 59-63)

[claim 4] Ridgeway teaches a method wherein the data is transmitted telephonically. (col. 5, lines 61-67; col. 9, lines 19-28)

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[claim 5] Ridgeway teaches a method wherein the triggers are selected from the group comprising the presence of data, the absence of data, the value of the data and the value of the trigger limit. (Figure 3; col. 7, lines 55-67; col. 8, lines 19-27; col. 10, lines 55-65)

[claim 6] Ridgeway teaches a method wherein the trigger types include home test reminder, data collection reminder or emergency alerts. (Figure 3; col. 7, lines 55-67; col. 8, lines 19-27; col. 10, lines 55-65)

[claim 7] Ridgeway teaches a device for acquiring data related to a person's healthcare habits comprising:

- (a) a module adapted to be opened and closed; (Figure 2; col. 6, lines 42-63)
- (b) at least two sensors connected to the module; (Figure 1; col. 6, lines 1-12)
- (c) indicating means connected to the module; (Figure 2; col. 6, line 52-63; col. 7, lines 22-33)
- (d) a memory for storing data connected to the first module; and (col. 9, lines 29-63)
- (e) means for transmitting the data from the module to a remote central location. (col. 5, lines 52-67; col. 7, lines 11-21)

[claim 9] Ridgeway teaches a device wherein the data is transmitted telephonically. (col. 5, lines 61-67; col. 9, lines 19-28)

[claim 10] Ridgeway teaches a device that includes an indicating means comprising at least one indicating light. (Figure 2; col. 5, lines 30-40: LED indicator power on light)

[claim 11] Ridgeway teaches a device wherein the indicating means comprises at least one sound emitting means. (col. 7, lines 11-32; col. 11, lines 1-18)

[claim 12] Ridgeway teaches a device further comprising:

- a second module adapted to receive the first module/ means for transmitting the data between the first module and second module; and (Figure 1; col. 5, lines 52-67)
- a device for accessing the second module; (Figure 1; col. 5, lines 52-67; col. 6, lines 1-12)
- means for transmitting the data between a second module and a remote central location. (Figure 1; col. 5, lines 44-67)

[claim 14] Ridgeway teaches a device for acquiring data related to a person's healthcare habits comprising:

- a first module adapted to receive a second module/means for transmitting the data between a first module and second module; and (Figure 1; col. 5, lines 52-67)
- a memory for storing data connected to the first module; (col. 9, lines 29-63)
- a second module adapted to receive the first module/ means for transmitting the data between the second module and first module; (Figure 1; col. 5, lines 52-67)
- an identification device capable of being used with the first module; and (col. 9, lines 65-col. 10, line 19)
- means for transmitting the data from the first module to a remote central location. (col. 5, lines 52-67; col. 7, lines 11-21)

[claim 16] Ridgeway teaches a device wherein the second module includes a glucometer or blood pressure apparatus. (Figure 2; col. 2, lines 6-12)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ridgeway in view of Kutzik et al (USPN 5,692,215--hereinafter Kutzik).

[claim 8] Ridgeway teaches a device wherein the memory stores a plurality of data, (col. 9, lines 29-63), but does not expressly disclose that the memory stores data regarding the opening and closes of the module. However, Ridgeway does suggest that the system may be custom programmed to record any parameters the physician deems necessary. (col. 8, lines 13-23; col. 10, lines 46-51) Kutzik teaches a system/device wherein information regarding the opening and closing of a module is recorded (col. 9, lines 7-24; lines 32-24) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/device of Ridgeway with the teaching of Kutzik to record information regarding the opening and closing of a system module. As suggested by Kutzik, one would have been motivated to include this feature to ensure that the patient complies with a predetermined regimen requiring the use of the module. (col. 9, lines 43-45)

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8. Claims 13 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Ridgeway in view of Official Notice.

[claim 13] Ridgeway teaches a device for accessing the second module (Figure 1; col. 5, lines 52-67; col. 6, lines 1-12: e.g. communication links, other monitoring devices), but does not expressly disclose that the device for accessing the second modules is selected from the group comprising a magnetic card reader, a barcode reader, a smart card reader or a biometric reader. However, it is noted that the use of such devices (smart card readers, magnetic card readers, barcode readers, or biometric readers) for providing restricted access is well known in the medical arts. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Ridgeway to include one such access/identification device to access one of the system modules. As suggested by Ridgeway, one would have been motivated to include this feature to automatically log all subscriber home health parameter measurement activities, maintain the stored measurement data protected from subscriber modification (col. 4, lines 52-54) and to verify the subscriber's well-being (col. 4, lines 62-64).

[claim 15] Ridgeway teaches the device of claim 14, as explained in the rejection of claim 14, but does not expressly disclose that the identification device is selected from the group comprising a magnetic card reader, a barcode reader, a smart card reader or a biometric reader. However, it is noted that the use of such devices (smart card readers, magnetic card readers, barcode readers, or biometric readers) for providing restricted access and identifying information is well known in the medical arts. At the

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time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Ridgeway to include one such access/identification device to access one of the system modules. As suggested by Ridgeway, one would have been motivated to include this feature to automatically log all subscriber home health parameter measurement activities, maintain the stored measurement data protected from subscriber modification (col. 4, lines 52-54) and to verify the subscriber's well-being (col. 4, lines 62-64).

9. Claims 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Ridgeway in view of Fu (USPN 4,803,625).

[claim 17] Ridgeway teaches a device wherein the second module may include plurality of components to track patient behaviors (Figure 2; col. 2, lines 6-12), but does not expressly disclose that the second module is selected from the group comprising a stool analyzer, an X-ray machine, an EKG machine, a fat analyzer or an office visit tracker. Fu teaches a system wherein a second module includes an electrocardiogram (EKG) machine. (Figures 1-2; col. 5, lines 7-32) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system/device of Ridgeway with the teaching of Fu to include other devices, such as an electrocardiogram machine. As suggested by Fu, one would have been motivated to include this feature to provide better tracking of the vital signs of the patient, and a complete log of vital signs to detect any abnormal trends. (Fu: col. 4, line 64-col. 5, line 2)

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Crawford, Jr. (USPN 5,331,549) teaches a medical monitoring system that alerts hospital staff on the status multiple patients.
- Stutman et al (USPN 5,416,695) teach a monitoring system that allows physicians to set patient medical parameters/thresholds remotely.
- Ridgeway (USPN 5,710, 551) teaches a medication compliance system.
- Sekura (WO 98/49659) teaches a system for ensuring that patients comply with a medication regimen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is 703-305-0108. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP



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PRIMARY EXAMINER